Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in December 2000.

New Approvals

NADA Number: 141-148

Trade Name:	Deccox® plus Rumensin®
Ingredients:	Decoquinate, monensin
Sponsor:	Alpharma, Inc.
Approval Date:	November 16, 2000
Status:	Over-the-counter
Route:	Oral
Species:	Cattle being fed in confinement for slaughter
Drug Form:	Type A Medicated Article to make Type B and C medicated feeds.
Concentration:	Decoquinate – 27.2 grams per pound of Type A Medicated Article, monensin – 20, 30, 45, 60, 80, or 90.7 grams per pound of Type A Medicated Article
Indications:	For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* and increased feed efficiency in cattle being fed in confinement for slaughter.
Tolerance:	21CFR556.170: Decoquinate: A tolerance of 2 ppm for residues of decoquinate in uncooked edible tissues other than skeletal muscle and 1 ppm in skeletal muscle. An Acceptable Daily Intake (ADI) of 0.075 milligram per kilogram of body weight per day has been established. 21CFR556.420: Monensin: A tolerance of 0.05 ppm for negligible residues of monensin in the edible tissues. An ADI of 0.0125 milligram per kilogram of body weight per day has been established.
Withdrawal:	Zero days

21CFR 558.195 and 558.355

Suitability Petition Action

Number:	00P-1655/CP1
Sponsor:	Highland VetPharma, LLC
Petition:	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone (Phenylbute®), Phoenix Scientific, Inc., NADA 091-818 by the following characteristics: The generic product will consist of a different dosage form (chewable tablet) from the pioneer.
Action:	Filed on December 6, 2000.